

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

AF/3731
#

Applicant: Timothy Wells, et al. Examiner: Jessica R. Baxter
Serial No.: 09/865,774 Group: Art Unit 3731
Filed: May 25, 2001 Docket: 203-2764 (2620)
For: TROCAR ASSEMBLY WITH
CUSHIONED ACTIVATOR Dated: September 3, 2003

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RECEIVED

SEP 10 2003

TECHNOLOGY CENTER R3700

TRANSMITTAL OF APPELLANTS' BRIEF

Sir:

Enclosed please find APPELLANTS' BRIEF in triplicate.

Also enclosed is a check in the amount of \$320.00 to
cover the appeal fee.

If the enclosed check is insufficient for any reason or
becomes detached, please charge the required fee under 37 C.F.R.
§ 1.17 to Deposit Account No. 50-2140. Also, in the event any
additional extensions of time are required, please treat this
paper as a petition to extend the time as required and charge
Deposit Account No. 50-2140. TWO (2) COPIES OF THIS SHEET ARE
ENCLOSED.

Respectfully submitted,

Christopher G. Trainor

Christopher G. Trainor
Reg. No. 39,517
Attorney for Applicant(s)

CARTER, DELUCA, FARRELL & SCHMIDT, LLP
445 Broad Hollow Road, Suite 225
Melville, New York 11747
Tel (631) 501-5700
Fax (631) 501-3526

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail,
postpaid in an envelope, addressed to the: Mail Stop Appeal Brief - Patents, Commissioner for Patents, P.O. Box
1450, Alexandria, VA 22313-1450.

Dated: September 3, 2003

Christopher G. Trainor
Christopher G. Trainor



PATENT
Atty. Docket No. 2620 (203-2764)

#15
CWH 9/25/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Timothy Wells, et al.

EXAMINER: Jessica R. Baxter

SERIAL NO.: 09/865,774

GROUP ART UNIT: 3731

FILED: May 25, 2001

DATED: September 3, 2003

FOR: **TROCAR ASSEMBLY WITH CUSHIONED ACTIVATOR**

Commissioner for Patents
P.O. Box 1450
Alexandria, Va. 22313-1450
Mail Stop Appeal Brief - Patents

RECEIVED

SEP 10 2003

TECHNOLOGY CENTER R3700

BRIEF ON APPEAL

Sir:

This is an appeal from a Final Rejection, dated March 3, 2003 for the above- identified application. This Brief is accompanied by the requisite fees set forth in 37 C.F.R. §1.17(c).

I. REAL PARTY IN INTEREST

The real party in interest for this application is United States Surgical, a Division of Tyco Healthcare Group LP.

II. RELATED APPEALS AND INTERFERENCES

There are no other related appeals or interferences for this application.

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postpaid in an envelope, addressed to Mail Stop: Appeal Brief, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on September 3, 2003.

Dated: September 3, 2003

Christopher G. Trainor
Christopher G. Trainor

09/09/2003 AXONDAF1 00000010 09865774

01 FC:1402

320.00 07

III. STATUS OF CLAIMS

Independent Claim 1 and dependant Claims 2-10 are pending in this application and each of these Claims stands finally rejected as set forth in the Examiner's Final Rejection dated March 3, 2003.

IV. STATUS OF AMENDMENTS

A request for reconsideration was filed on May 30, 2003, and has been considered by the Examiner. No amendments have been filed after the final Office Action dated March 3, 2003.

V. SUMMARY OF THE INVENTION

The present disclosure is directed to a trocar assembly which includes an obturator having a sharpened tip at one end and a hand grip secured to the other end. (Specification page 2, line 13). The hand grip includes a cushioned member. (Specification page 2, line 14-15). The cushioned member is secured to at least one pressure contact region of the hand grip. (Specification page 4, lines 1-2). The pressure contact regions of the hand grip include those areas which the surgeon grasps or applies pressure to during manipulation of the trocar assembly or insertion of the obturator through body tissue into the body cavity. (Specification page 4, lines 2-5). The cushioned member on the pressure contact regions of the hand grip lessens, or alleviates, the impact on the surgeons' hands during operation of the trocar. (Specification page 4, lines 15-18). The cushioned member is preferably formed of a thermoplastic elastomer material, and can be over-molded onto the hand grip. (Specification page 4,

lines 5-8). In another preferred embodiment, the cushioned member can also have slip resistant properties, which improves the surgeons' grip on the trocar, including in the presence of fluids. (Specification page 4, lines 18-21). The cushioned member may also have a textured, roughened or ridged surface to enhance the slip resistant properties. (Specification page 4, lines 21-22).

In alternative preferred embodiments, the cushioned member may be formed of other cushioned or pliant materials, for example, elastomeric or synthetic materials, including isoprenes or nitrile or silicon containing materials, etc. (Specification page 4, lines 9-11). The cushioned member can alternatively be attached to the hand grip portion using other known fastening techniques, including, for example, physical, chemical, or mechanical techniques. (Specification page 2, lines 19- 22).

VI. ISSUE

The following issue is on appeal:

Whether Claims 1-10 are unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 5,674,237 to Ott in view of U.S. Patent No. 5,928,154 to Silber.

VII. GROUPS OF CLAIMS

Group 1: Claims 1-10.

VIII. ARGUMENT

Claims 1-10 were finally rejected as being unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 5,674,237 ("Ott") to Ott in view of U.S. Patent No.

5,928,154 ("Silber") to Silber et al. Appellants contend that each of these Claims is patentably distinct from the combined references.

To ensure that the standard of nonobviousness is properly determined, considerations to be applied to each case have been delineated by the Court, as set forth in Graham v. John Deere. (383 U.S. 1, 148 USPQ 459 (1966)). The considerations to be applied form the following three pronged test: (a) determination of the scope and contents of the prior art; (b) determination of the differences between the claims at issue and the prior art; and, (c) determination of the level of ordinary skill in the pertinent art. In addition, any evidence of secondary considerations, such as failure of others to produce the article in question, long felt but unsolved need, and commercial success, for example, can be evaluated to develop a full, rounded view of the pertinent art surrounding the claims in question. See, Manual Of Patent Examining Procedure ("MPEP") §2141.

To apply the Graham test, several basic tenants of patent law must be taken into consideration. Any prior art references cited must be evaluated as a whole, and portions for or against, or teaching away from, the argued position must be considered. See, e.g. Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 230 USPQ 416 (Fed. Cir. 1986), cert. denied 484 US 823 (1987), on remand, 10 USPQ 2d 1929 (N.D. Calif. 1989). To combine two or more prior art references, the prior art must provide some teaching, suggestion or incentive to support the combination. In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). The use of hindsight is "a forbidden ex post analysis"

method of “decomposing an invention into its constituent elements” and can not be used to find elements in the prior art to reassemble as anticipatory to the invention. See, In re Mahurkar Patent Litigation, 831 F. Supp. 1354, 28 USPQ2d 1801 (N.D. Ill. 1993). Where a reference is silent on an asserted inherent characteristic, any extrinsic evidence must be clear that missing descriptive matter is necessarily present in the thing described and that it would be recognized by those of ordinary skill in the art. Continental Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

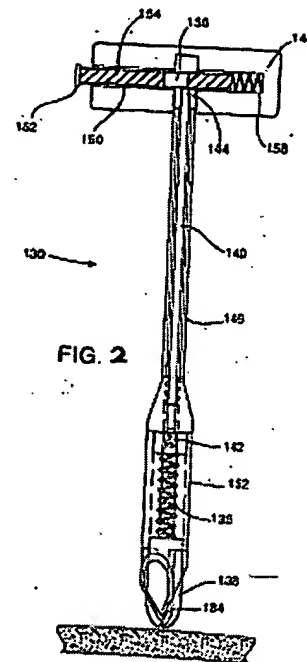
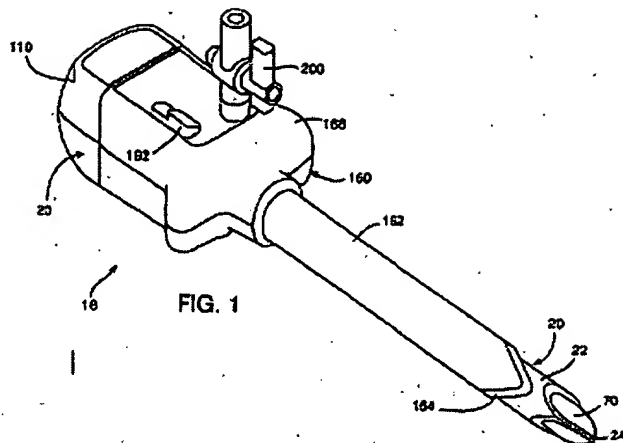
In rejecting Claims 1-10 in the Final Office Action dated March 3, 2003, the Examiner stated the following:

“Ott discloses a trocar assembly comprising an obturator (see FIG. 2 obturator 22), a sharpened tip (see FIG. 2 tip 24) and a hand grip (see FIG. handle 110). Ott discloses the claimed invention except for the cushioned member positioned on at least one contact surface of the hand grip. Silber teaches that a cushioned member is provided on the hand grip in order to enable the instrument’s user to maintain control while applying minimal gripping force (see Column 3 lines 17-23). Although Silber discloses that the member is substantially non compressible (see Column 3 lines 17-19), Silber later discloses that the material used would have a low durometer and thus has a cushioning effect (see Column 3 lines 63- 64). In addition, the preferred materials of the claimed invention such as Santoprene, silicone, and nitrile are specifically mentioned as being used to form the cushioned member (see Column 8 lines 28-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add a cushioned member to the hand grip of Ott’s trocar assembly in order to enable the instrument’s user to maintain control of the instrument while applying minimal gripping force.”

Claim 1 requires a trocar assembly formed of an obturator having a sharpened tip on one end of the obturator's longitudinal axis, a hand grip on the opposite end, and a cushioned member is positioned on at least one pressure contact surface of the hand grip. (Specification page 7, lines 2- 6). Claims 2 through 10 depend, either directly or indirectly, from Claim 1.

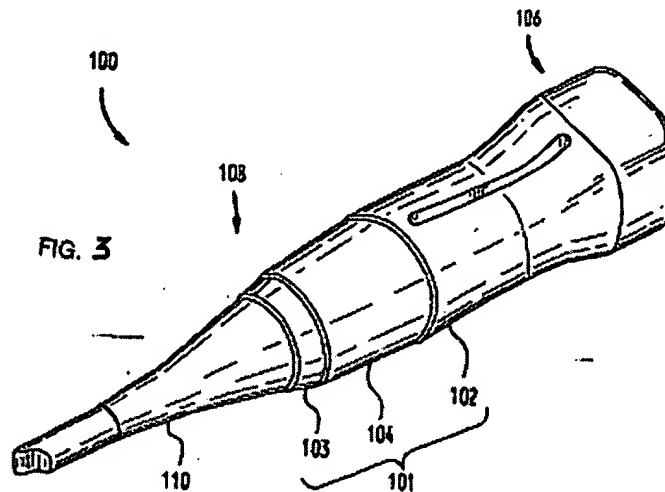
Appellants respectfully disagree with Examiner's interpretation of the Silber patent. Silber does not disclose a cushioned member positioned on at least one pressure contact surface of the hand grip. Furthermore, nothing in the Ott or Silber patents provides a teaching or incentive to support the combination.

The Ott patent (shown in Figs. 1 and 2) discloses a trocar which provides a safety shield covering the cutting tip of the obturator, and can have a safety locking mechanism that prevents unintended withdrawal of a safety shield. The safety shield has three distally extending fingers 138 which extend through openings on the face of the pyramidal cutting tip 134. (Col. 3, lines 53-57; Col. 9, lines 24-35). The safety shield is ellipsoidal in shape on the distal end to facilitate penetration of tissue and reduce frictional resistance to deployment of the shield. (Col. 3, lines 57- 61). The safety locking mechanism prevents additional invaginations around the puncture site and allows the safety shield to withdraw only once as the trocar passes through the tissue to protect internal organs. (Col. 3, lines 33- 42). Withdrawal of the safety shield is activated by a release button 152 which is located on the trocar handle 110. (Col. 3, lines 42- 44).



Silber discloses an ultrasound probe housing with a reduced control pressure grip 104 (shown in Fig. 3). The grip coating layer is formed substantially around a length of the probe housing, approximately midway along the length of the probe. (Col. 3, lines 46- 53). The grip coating layer is formed of a substantially **non-compressible** material (column 3 line 17-19). Preferably, the reduced control pressure grip is a substantially thin, rigid, elastomeric coating having a high coefficient of friction, a high chemical resistance, good cut resistance and excellent adhesion to the underlying probe. (Col. 3, lines 59- 64). The grip coating layer is preferably formed of a low durometer thermoplastic elastomer. (Col. 7, lines 58- 67). To join the grip coating layer to the probe, it is mechanically interlocked between inner 102 and rear 103 housings, forming a gas and liquid impermeable seal to protect the probe from repeated sterilizations. The surface of the grip coating layer is preferably flush with the surface of the housing resulting in a continuously smooth casing surface that minimizes the

accumulation of cleaning solvents, coupling gels and contaminants in any junction between the grip and the probe housing. (Col. 6, lines 25- 31). The grip coating layer can also be used to form an external casing to the probe. (Col. 3-4, lines 65- 67, 1-7). The grip coating layer enables the user to maintain control over the probe while applying minimal gripping force, thereby preventing fatigue. (Col. 5, lines 41- 45).



Claims 1-10

As discussed above, Claim 1 recites a trocar assembly and requires an obturator having a hand grip. The hand grip has a cushioned member on at least one pressure contact surface of the hand grip. The cushioned member is preferably made of a thermoplastic elastomer. (Specification page 4, lines 4-5). The cushioned member lessens the impact on a surgeon's hand during operation of the surgical instrument. (Specification page 4, lines 15-18). The Ott patent is directed to a trocar device with a shield for the cutting tip. (Col. 3, lines 16-19). The cushioned member of Claim 1 differs greatly from the safety shield features of the Ott patent, which cover the sharpened cutting tip of the obturator.

The Silber patent also fails to disclose a cushioned member on at least one pressure contact surface of the obturator hand grip. The Silber reference discloses a grip that is formed substantially circumferentially around a length of an ultrasound probe, which allows the user to apply a minimal gripping force. This minimal gripping force is intended to allow the probe user to maintain control of the probe and avoid occupational injuries, regardless of whether the probe user is right or left handed. The Silber grip coating layer is a substantially **non-compressible**, thin, rigid, elastomeric coating having a high coefficient of friction, and excellent adhesion to the underlying probe housing. By contrast, Claim 1 requires a cushioning member on at least one pressure contact surface of the hand grip. Whereas the cushioning member lessens the impact on the surgeon's hand while applying force, the Silber grip coating layer is a thin rigid coating for maintaining control over the probe and decreasing the gripping force necessary to operate the probe. Silber does not disclose a cushioning member, as required by Claim 1. Silber's teaching of a thin, rigid, **non-compressible** coating teaches away from Claim 1, rather than suggesting it. Therefore, the Ott and Silber references cannot be combined and cited against Claim 1.

Additionally, although Silber does disclose that the grip coating layer is preferably a low durometer thermoplastic elastomer (column 3, lines 63-64), Silber immediately precedes that statement with the following:

"More specifically, the reduced control-pressure grip layer is preferably a substantially thin, rigid elastomeric coating having a high coefficient of friction, a high chemical resistance, good cut resistance, and excellent adhesion to the underlying probe housing"

Taking these statements together, as they must be taken, Silber provides a substantially non-compressible, thin, rigid coating of a low durometer thermoplastic elastomer as a grip coating layer. Given these parameters, the coating layer of Silber could not provide a cushioning effect, even if it were formed of a low durometer thermoplastic material. Therefore, Silber's coating layer can not constitute a "cushioned member" as recited in Claim 1. If one were to attempt to modify Ott in view of Silber, as suggested by the Examiner, the resulting modified device would have a thin rigid non-compressible coating layer over a handle. Such a coating layer would not lessen the impact on a surgeon's hand while inserting a trocar through a patient's tissue. To infer that Silber's coating layer has an inherent "cushioning member", it must be clear that the missing descriptive matter is necessarily present in the provided description. Continental Can Co. USA at 1268. Silber entirely lacks descriptive matter on a cushioning member for a hand grip.

The objective of Silber runs counter to the use of the Ott patent, which requires great force to insert the trocar through layers of tissue. The safety shield and safety locking mechanism of the Ott patent does not require, or suggest, a grip layer of a thin, rigid elastomeric coating. Because of their opposing goals, no suggestion or incentive exists to attempt to combine the Ott and Silber patents. See, In re Bond, supra; In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). Silber does not provide such evidence and deliberately teaches away by providing a thin, rigid coating.

Accordingly, Silber can not be combined with Ott to add a “cushioned member” to the trocar disclosed in Ott.

Trocars are well known in the art, and are known to cause an impact on a surgeon's hands during the insertion of the surgical device through a patient's tissue. However, Ott, and others, have failed to previously provide a cushioned mechanism to lessen such an impact although surgeons were continually exposed to impact. Alone, the Ott patent fails to disclose or suggest the improvements provided by Claim 1. Ott's teachings are directed to very different safety features for a surgical instrument, as described above. Viewed separately, Silber's disclosure bears no resemblance or suggestion of the device in Claim 1. Ott's safety trocar and Silber's ultrasound probe housing with reduced control pressure grip differ greatly from each others' operation, structure and use. There exists no motivation or incentive to attempt to combine the two references as one. Clearly, such an attempt is done in hindsight erroneously. The use of hindsight can not be used to try to reassemble elements as anticipatory to the claims at question and is therefore improper. In re Mahurkar Patent Litigation, supra.

For the reasons delineated above, appellants believe that Claim 1 is patentably distinct from both Ott and Silber, whether taken singularly or in combination, and is in condition for allowance. Claims 2-10 depend directly or indirectly from Claim 1. For the reason discussed above with respect to Claim 1, inter alia, Appellants believe that Claims 2-10 are in condition for allowance, as well.

IX. CONCLUSION

In view of the foregoing analysis and remarks, Appellants respectfully submit that all of the claims pending in this application, namely Claims 1-10, are in condition for allowance. An early and favorably reconsideration of this application is respectfully requested.

Respectfully submitted,



Christopher G. Trainor
Reg. No. 39,517
Attorney for Appellants

Carter DeLuca Farrell & Schmidt, LLP
445 Broad Hollow Road, Suite 225
Melville, New York 11747
Telephone No. (631) 501-5700
Facsimile No. (631) 501-3526

X. APPENDIX OF CLAIMS

1. A trocar assembly comprising:

an obturator defining a longitudinal axis and having first and second ends, a sharpened tip positioned on the first end of the obturator and a hand grip positioned on a second end of the obturator opposite the first end, and a cushioned member positioned on at least one pressure contact surface of the hand grip.
2. A trocar assembly according to Claim 1, wherein the cushioned member is formed from a thermoplastic elastomer.
3. A surgical instrument according to Claim 2, wherein the cushioned member is over-molded onto the hand grip.
4. A trocar assembly according to Claim 1, wherein the cushioned portion is formed from an elastomeric material.
5. A trocar assembly according to Claim 1, wherein the cushioned member is secured to the hand grip with an adhesive.
6. A trocar assembly according to Claim 1, wherein the cushioned member is secured to the hand grip by welding.
7. A trocar assembly according to Claim 1, wherein the cushioned member is formed from a slip resistant material.
8. A trocar assembly according to Claim 4, wherein the elastomeric material is selected from the group consisting of isoprene, nitrile and silicon.

9. A trocar assembly according to Claim 1, wherein the hand grip is formed from a thermoplastic material and the cushioned member is formed from an elastomeric material.
10. A trocar assembly according to Claim 1, wherein the cushioned member is over-molded onto the hand grip.